



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 30 1999

4 8 5 5 '00 JAN 28 P2 :37

Ms. Susan Carlson
Vice President
J.R. Carlson Laboratories, Inc.
15 College
Arlington Heights, Illinois 60004-1985

Dear Ms. Carlson:

This is in response to your letter of September 7, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that J.R. Carlson Laboratories, Inc., is making certain statements for a product you assert is a dietary supplement, namely, Carlson Easy Soy® Gold Drink Mix.

We have reviewed your submission for this product and have concluded that it, while asserted to be a dietary supplement, is labeled and represented for use as a conventional food, in that it appears to be a beverage base and its label bears nutrition labeling for conventional foods.

The Act, as amended by the Dietary Supplement Health & Education Act of 1994, defines the term "dietary supplement" to exclude products represented for use as conventional foods and distinguishes dietary supplements from conventional foods in many important ways, e.g., different requirements with respect to safety, to the types of claims that can be made, and to the kind of information that must be provided in the nutrition label. Given the representations made for this product, the product does not appear to be a dietary supplement within the meaning of 21 U.S.C. 321(ff) and cannot continue to be marketed as a dietary supplement.

Under the Act, any ingredient intentionally added to a conventional food like a beverage must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. FDA would expect that the ingredients contained in Carlson Easy Soy® Gold Drink Mix are approved food additives or GRAS for use in conventional food.

97S-0163

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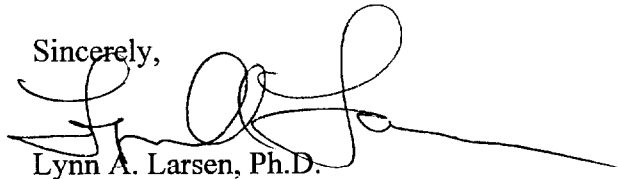
We are also concerned about the statements you are making on the labels and in the labeling of your product, particularly the claims regarding the effect of the product on the cardiovascular system, cellular growth, hormonal balance, on well-being in women during certain times of life. If you intend to market this product as a food bearing claims of these kind, such claims must be in the form of an appropriate claim to affect the structure or function of the body and the claimed effect must be achieved through nutritive value or it must be an authorized health claim for a relationship between a substance and a disease.

In summary, a conventional food product like yours may be marketed as such, provided that the ingredients in this food meet the safety requirements of the Act, the product is properly labeled with a correct nutrition facts panel, any claims to affect the structure or function of the body are achieved through nutritive value, and any diet/substance-disease claims are authorized as health claims.

Please advise us as soon as possible whether you intend to continue to market this product and if so, how you intend to bring it into compliance, including your basis for concluding that the ingredients and claims meet the safety and labeling requirements of the Act.

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lynn A. Larsen', with a long horizontal flourish extending to the right.

Lynn A. Larsen, Ph.D.

Director

Division of Programs and Enforcement Policy

Office of Special Nutritionals

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Chicago District Office, Office of Compliance, HFR-MW140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-1

HFS-3

HFS-4

HFS-22 (CCO)

HFS-150 (Wilkening, Foret, Kelker)

HFS-206 (GPauli)

HFS-456 (r/f, File)

HFS-450 (r/f, File)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Dorsey, Nickerson, Barnett)

HFV-228 (SBenz)

r/d:HFS-456:RMoore:9/29/99

revised per HFS-455:LLarsen:9/30/99

revised per HFS-450:EYetley:10/5/99

revised per HFS-150:JForet:10/5/99

f/t:HFS-456:rjm:12/30/99:docname:67367.adv:disc43

Carlson[®]

September 7, 1999



Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, D.C. 20204

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of a statement of nutritional support in the labeling of Carlson Easy Soy Gold Drink Mix. Carlson Division of J. R. Carlson Laboratories, Inc., Arlington Heights, Illinois 60004, is the distributor of Carlson Easy Soy Gold Drink Mix.

Statement being made in the labeling of Carlson Easy Soy Gold Drink Mix.

"Isoflavones are known for a variety of health benefits such as supporting cardiovascular function, promoting normal cellular growth, maintaining hormonal balance, and acting as antioxidants. Scientific research focuses on women's health, and suggest that soy isoflavones may even promote and support a feeling of well-being during the challenging phases of a woman's lifecycle."

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete; and that J. R. Carlson Laboratories, Inc. possesses substantiation that the statements are truthful and not misleading.

J. R. Carlson Laboratories, Inc.

By: 
Susan Carlson, Vice President

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Isoflavones are known for a variety of health benefits such as supporting cardiovascular function, promoting normal cellular growth, maintaining hormonal balance, and acting as antioxidants. Scientific research focuses on women's health, and suggests that soy isoflavones may even promote and support a feeling of well-being during the challenging phases of a woman's lifecycle.*

Carlson Easy Soy Gold Drink provides protein plus an array of isoflavones including genistein, daidzein, and glycitein; along with other phytonutrients including saponins, genistin, daidzin, and glycitin.

- ✓ High quality, protein source providing essential and non-essential amino acids
- ✓ High in isoflavones
- ✓ Fat-free. Cholesterol-free.
- ✓ Contains Novasoy™ Isoflavone concentrate (Trademark of A.D.M.)
- ✓ Quality backed with the Carlson Name
- ✓ A delicious way to get all of the benefits of soy!

Directions For Use: Add 1 rounded scoopful to 6 - 8 ounces of water or your favorite beverage. Stir or shake briskly. For a smoother drink, add ice and mix in an electric blender. Fresh fruit may be added.

POTENCY AND QUALITY GUARANTEED



Distributed by Carlson Division of
J.R. Carlson Laboratories, Inc.
Arlington Hts., IL 60004-1985

* These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Nutrition Facts

Serving Size 1 rounded scoopful (approx. 30 grams)
Servings Per Container 19

Amount Per Serving	
Calories 120	Calories from Fat 0
% Daily Value	
Total Fat 0 g	0%
Cholesterol 0 mg	0%
Sodium 200 mg	8%
Potassium 25 mg	1%
Total Carbohydrates 10 g	3%
Sugars 8 g	
Protein 16 grams	32%
Calcium	4%
Iron	15%
Phosphorus	15%

Soy Isoflavones providing:	50 mg	not estab.
Genistein & Genistin	26.6 mg	not estab.
Daidzein & Daidzin	17.7 mg	not estab.
Glycitein & Glycitin	3.7 mg	not estab.
Saponins	2.0 mg	not estab.

☆ Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

		Calories	2,000	2,500
Total Fat	Less than	65g	80g	
Sat. Fat	Less than	20g	25g	
Cholesterol	Less than	300mg	300mg	
Sodium	Less than	2,400mg	2,400mg	
Potassium		3,500mg	3,500mg	
Total Carbohydrate		300g	375g	
Dietary Fiber		25g	30g	
Protein		50g	65g	

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

Ingredients: Protein blend of soy protein isolate, soy concentrate, soy isoflavone extract, fructose, natural vanilla cream flavor.

Carlson Easy Soy Gold Drink Mix is free of corn, yeast, wheat, and is formulated without the use of preservatives, artificial flavors or colors.

EasySoy®

DRINK MIX Gold

Rich in:
Protein and Isoflavones

NATURAL VANILLA FLAVOR

NET WEIGHT 20 oz. (568 g.)